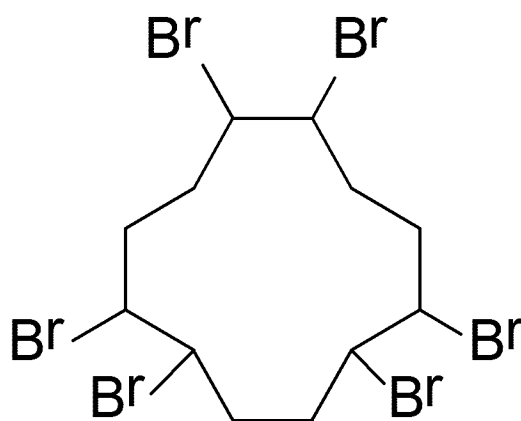




Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster



CASRN	NAME
25637-99-4	Hexabromocyclododecane
3194-55-6	1,2,5,6,9,10-Hexabromocyclododecane
3194-57-8	1,2,5,6-Tetrabromocyclooctane

June 2017

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Docket

Supporting information can be found in public docket: [EPA-HQ-OPPT-2016-0735](#).

Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the United States Government.

ABBREVIATIONS

°C	Degrees Celsius
atm	Atmosphere(s)
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BFRIP	Brominated Flame Retardant Industry Panel
C&D	Construction and Demolition
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Candidate Contaminant List
CDR	Chemical Data Reporting
CDT	Cyclododecatriene
CEC	Commission for Environmental Cooperation
cm ³	Cubic Centimeter(s)
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CSCL	Chemical Substances Control Law
EC	European Commission
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EPS	Expanded Polystyrene
ESD	Emission Scenario Document
FHSA	Federal Hazardous Substances Act
g	Gram(s)
HAP	Hazardous Air Pollutant
HBCD	Hexabromocyclododecane
HIPS	High Impact Polystyrene
HPV	High Production Volume
IRIS	Integrated Risk Information System
kg	Kilogram(s)
K _{oa}	Octanol:Air Partition Coefficient
L	Liter(s)
lb	Pound
LCD	Liquid-Crystal Display
Log K _{oc}	Logarithmic Organic Carbon:Water Partition Coefficient
Log K _{ow}	Logarithmic Octanol:Water Partition Coefficient
m ³	Cubic Meter(s)
µg	Microgram(s)
mmHg	Millimeter(s) of Mercury
MSDS	Material Safety Data Sheet
MSWLF	Municipal Solid Waste Landfill
NEI	National Emissions Inventory
NICNAS	National Industrial Chemicals Notification and Assessment Scheme

NIH	National Institute of Health
NIOSH	National Institute of Occupational Safety and Health
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
PEC	Predicted Environmental Concentration
PFIA	Problem Formulation and Initial Assessment
POD	Point of Departure
POP	Persistent Organic Pollutant
POTW	Publicly Owned Treatment Works
ppm	Part(s) per Million
PVC	Polyvinylchloride
QC	Quality Control
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SDS	Safety Data Sheet
SHGB	Sex Hormone Binding Globulin
SIDS	Screening Information Data Set
SIPS	Structural Insulated Panels
SNUR	Significant New Use Rule
SVHC	Substance of Very High Concern
TCCR	Transparent, Clear, Consistent, and Reasonable
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
U.S.	United States
UNEP	United Nations Environment Programme
WEEE	Waste Electrical and Electronic Equipment
WWTP	Wastewater Treatment Plant
XPS	Extruded Polystyrene
XPSA	Extruded Polystyrene Association

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.” In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency’s initial chemical risk evaluations ([81 FR 91927](#)), as required by TSCA § 6(b)(2)(A). HBCD was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for HBCD.

This document presents the scope of the risk evaluation to be conducted for HBCD. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify “circumstances” that constitute “conditions of use” for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for HBCD. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

The cyclic aliphatic bromide cluster chemicals, including HBCD (Chemical Abstracts Service Registry Number [CASRN] 25637-99-4), 1,2,5,6,9,10-hexabromocyclododecane (1,2,5,6,9,10-HBCD; CASRN 3194-55-6) and 1,2,5,6-tetrabromocyclooctane (CASRN 3195-57-8) are flame retardants. Uses for 1,2,5,6-tetrabromocyclooctane have not been identified. For the purposes of this scope document, the use of “HBCD” refers to either CASRN 25637-99-4 or 3194-55-6, or both.

The primary use of HBCD is as a flame retardant in expanded polystyrene (EPS) foam and extruded polystyrene (XPS) foam in the building and construction industry for thermal insulation boards and laminates for sheathing products; however, it may also be used to a limited extent in plastics (additive)

and textiles (backcoating). Information gathered from research, industry and consumer product organizations, however, has led EPA to believe that HBCD is no longer used in consumer textile applications outside of the automotive industry.

A Problem Formulation and Initial Risk Assessment (PFIA) for the Cyclic Aliphatic Bromides Cluster was published for public comment in 2015; however, a draft risk assessment was not completed prior to the passing of amended TSCA. As in the 2015 PFIA document, EPA expects to review current published risk assessments and scenarios for workers, consumers, the general population and biota. EPA now also expects to consider the conditions of use as described in this scope document. Subsequent to the PFIA, HBCD has been listed on the Toxics Release Inventory (TRI); the first reporting year is 2017. EPA also promulgated a significant new use rule (SNUR) for use in consumer textiles [80FR 57293](#).

The initial conceptual models presented in Section 2 identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of the chemical.

This document presents the scenarios in which workers and occupational non-users may be exposed to HBCD during a variety of conditions of use. The manufacturing, processing, distribution and industrial and commercial use of HBCD could result in exposures to workers and occupational non-users via inhalation of particulates, dermal contact with particulates, ingestion of particulates that deposit in the upper respiratory tract and are swallowed or ingestion of HBCD following hand to mouth contact. Consumers and bystanders may also be exposed to HBCD via inhalation of particulates, dermal contact with HBCD in articles and oral exposure via ingestion of settled dust or mouthing of articles. For HBCD, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to the general population may occur from industrial releases. The manufacturing, processing, distribution and use of HBCD can result in releases to air, water, sediment and soil. EPA expects to consider exposures to the general population and environment via inhalation of air emitted from manufacturing, processing and use facilities and from water, sediments and soils that may receive releases or wastes from such facilities. As data suggest that HBCD is persistent and bioaccumulative, routes of exposure may include ingestion of water, breast milk, and edible aquatic and terrestrial biota.

HBCD has been the subject of numerous health hazard and risk assessments. Any existing assessments will be a starting point as EPA will conduct a systematic review of the literature, including new literature since the existing assessments, as available in *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, [EPA-HQ-OPPT-2016-0735](#)). Human health hazards of HBCD have been reviewed previously and include liver toxicity, thyroid toxicity, reproductive/developmental toxicity, neurotoxicity, immunotoxicity and sensitization/irritation, all of which EPA/OPPT expects to consider in the scope of the TSCA risk evaluation. HBCD hazards to fish,

aquatic plants, sediment invertebrates and terrestrial organisms have also previously been assessed. These hazards will be evaluated based on the specific exposure scenarios identified.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for HBCD. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of HBCD.

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for HBCD. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated in-depth will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.”

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for HBCD.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify “circumstances” that constitute “conditions of use” for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a

chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing, or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their life cycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant

information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to HBCD. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. EPA may evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any, further analysis might be necessary as part of risk evaluation.

Federal Laws and Regulations

HBCD is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

State Laws and Regulations

HBCD is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

Laws and Regulations in Other Countries and International Treaties or Agreements

HBCD is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A.3.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use,

hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected (see *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, [EPA-HQ-OPPT-2016-0735](#)) using the literature search strategy (see *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document*, [EPA-HQ-OPPT-2016-0735](#)) to ensure that EPA is considering information that has been made available since these evaluations were conducted.

A Problem Formulation and Initial Assessment (PFIA) for the Cyclic Aliphatic Bromides Cluster was published in 2015 ([U.S. EPA, 2015b](#)); however, a draft risk assessment was not completed. EPA/OPPT expects to review the public comments received on the 2015 PFIA during problem formulation. EPA/OPPT outlined plans to evaluate existing assessments in the 2015 PFIA for HBCD ([U.S. EPA, 2015b](#)), including those listed in Table 1-1 below. EPA/OPPT also outlined several exposure scenarios, including occupational exposure to HBCD during HBCD and polystyrene foam manufacture and processing; general population from releases to the environment; environmental exposure from releases to the environment; and consumer exposure from the use of products or articles containing HBCD in indoor environments.

Table 1-1. Assessment History of HBCD

Authoring Organization	Assessment
EPA assessments	
EPA, Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT)	Initial Risk Based Prioritization of High Production Volume Chemicals. Chemical/Category: Hexabromocyclododecane (HBCD) (2008)
EPA, OCSPP, OPPT	Hexabromocyclododecane (HBCD) Action Plan (2010)
EPA, OCSPP, OPPT	Flame Retardant Alternatives for Hexabromocyclododecane (HBCD) (2014b)
EPA, OCSPP, OPPT	Toxic Chemical Work Plan Problem Formulation and Initial Assessment for HBCD, Cyclic Aliphatic Bromides Cluster(2015b)
Other U.S.-based organizations	
Consumer Product Safety Commission (CPSC)	CPSC Staff Exposure and Risk Assessment of Flame Retardant Chemicals in Residential Upholstered Furniture (CPSC, 2001)
International	
Organisation for Economic Co-operation and Development (OECD), Screening Information Data Set (SIDS)	OECD SIDS Initial Assessment Profile (SIAP) (2007)

Authoring Organization	Assessment
European Commission (EC), European Chemicals Bureau	European Union Risk Assessment Report, Hexabromocyclododecane CASRN 25637-99-4. EINECS No: 247-148-4 (2008)
United Nations Environment Programme (UNEP); Stockholm Convention on Persistent Organic Pollutants (POPs)	Hexabromocyclododecane Draft Risk Profile (2010)
Environment Canada and Health Canada	Draft Screening Assessment of Hexabromocyclododecane (2011)
Australian Government Department of Health, National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	Priority Existing Chemical Assessment Report, Hexabromocyclododecane (2012)

1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard and human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens*, to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0735](#)) provides details about the data sources and search terms that were used in the initial search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0735](#)). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent

data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard) but within each data set, there are two broad categories or data tags: (1) *on-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. *Off-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0735](#)) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information - for example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0735](#)) and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0735](#)). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between HBCD and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use of HBCD. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

HBCD is a white odorless non-volatile solid that is used as a flame retardant. Technical HBCD is often characterized as a mixture of mainly three diastereomers, which differ only in the spatial disposition of the atoms. Commercial-grade HBCD may contain some impurities, such as tetrabromocyclododecene or other isomeric HBCDs ([UNEP, 2010](#)), which are not separately included in this scope. The density of HBCD is greater than that of water (2.24 g/cm³ at 20°C). It has low water solubility (66 µg/L at 20°C) and a log octanol:water partition coefficient (log K_{ow}) of 5.62.

Table 2-1. Physical and Chemical Properties of HBCD

Property	Value ^a	References
Molecular formula	C ₁₂ H ₁₈ Br ₆	
Molecular weight	641.7 g/mole	
Physical form	White solid; odorless	EINECS (2008)
Melting point	Ranges from approximately: 172-184°C to 201-205°C	EINECS (2008)
Boiling point	>190°C (decomposes)	EINECS (2008)
Density	2.24 g/cm ³	EINECS (2008)
Vapor pressure	4.7E-07 mmHg at 21°C	EINECS (2008)
Vapor density	Not readily available	EINECS (2008)
Water solubility	66 µg/L at 20°C	EINECS (2008)
Octanol:water partition coefficient (log K _{ow})	5.625 at 25°C	EINECS (2008)
Henry's Law constant	7.4E-06 atm-m ³ /mole (estimated)	U.S. EPA (2012a)
Flash point	Not readily available	EINECS (2008)

Property	Value ^a	References
Autoflammability	Decomposes at >190°C	EINECS (2008)
Viscosity	Not readily available	EINECS (2008)
Refractive index	Not readily available	EINECS (2008)
Dielectric constant	Not readily available	EINECS (2008)
^a Measured unless otherwise noted.		

2.2 Conditions of Use

TSCA § 3(4) defines the conditions of use as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”

2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., *Use and Market Profile for HBCD*, [EPA-HQ-OPPT-2016-0735](#)). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: HBCD*, [EPA-HQ-OPPT-2016-0735-0003](#)) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer; when distinguishable), distribution and disposal. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders) to provide an overview of conditions of use. EPA notes that some subcategories of use may be grouped under multiple CDR categories.

For the purposes of this scope, CDR definitions were used. CDR use categories include the following: “industrial use” means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. “Commercial use” means the use of a chemical or a mixture

containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. “Consumer use” means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use ([U.S. EPA, 2016b](#)).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting ([U.S. EPA, 2016b](#)), when the volume was not claimed confidential business information (CBI). The 2016 CDR reporting data for HBCD are provided in Table 2-2 for HBCD from EPA’s CDR database ([U.S. EPA, 2016b](#)).

Table 2-2. Production Volume of HBCD in CDR Reporting Period (2012 to 2015) ^a

Reporting Year		2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	CASRN 25637-99-4	1-10 million	1-10 million	1-10 million	1-10 million
	CASRN 3194-55-6	10-50 million	10-50 million	1-10 million	1-10 million
^a The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016b). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.					

Data reported for the CDR period for 2016 for HBCD indicate that between 1 and 10 million lbs of each CASRN was manufactured in or imported into the United States in 2015; the precise production volume is CBI ([U.S. EPA, 2017a](#)). For both CASRNs, site-specific production volumes for the 2011 reporting year were withheld as TSCA CBI.

2016 CDR data pertaining to facility and specific use are not yet publicly available ([U.S. EPA, 2016b](#)). Five sites are identified in the 2012 CDR database ([U.S. EPA, 2012b](#)) as manufacturers or importers of HBCD: Albemarle Corporation, BASF Corporation, The Dow Chemical Company and two sites where CBI was claimed ([U.S. EPA, 2012b](#)). Albemarle manufactures HBCD flame retardants ([Albemarle, 2000](#)). Both BASF and Dow Chemical indicate in the CDR data that they are importers; however, trade names of the BASF or Dow Chemical products that use or contain HBCD could not be found in a literature search. In 2011, two sites imported and three sites domestically manufactured at least one of the chemicals.

Since the 2012 CDR data were collected, industry has indicated either partial or complete replacement of HBCD in their product lines ([U.S. EPA, 2017c](#)). No data are available to quantify these changes.

Figure 2-1 depicts the initial life cycle diagram of HBCD from manufacture to the point of disposal. The initial life cycle diagram does not distinguish between industrial, commercial and consumer uses; EPA will further investigate and define the differences between these uses during risk evaluation. Based on 2012 CDR data ([U.S. EPA, 2012b](#)). EPA expects that HBCD is primarily used in the production of building and construction materials.

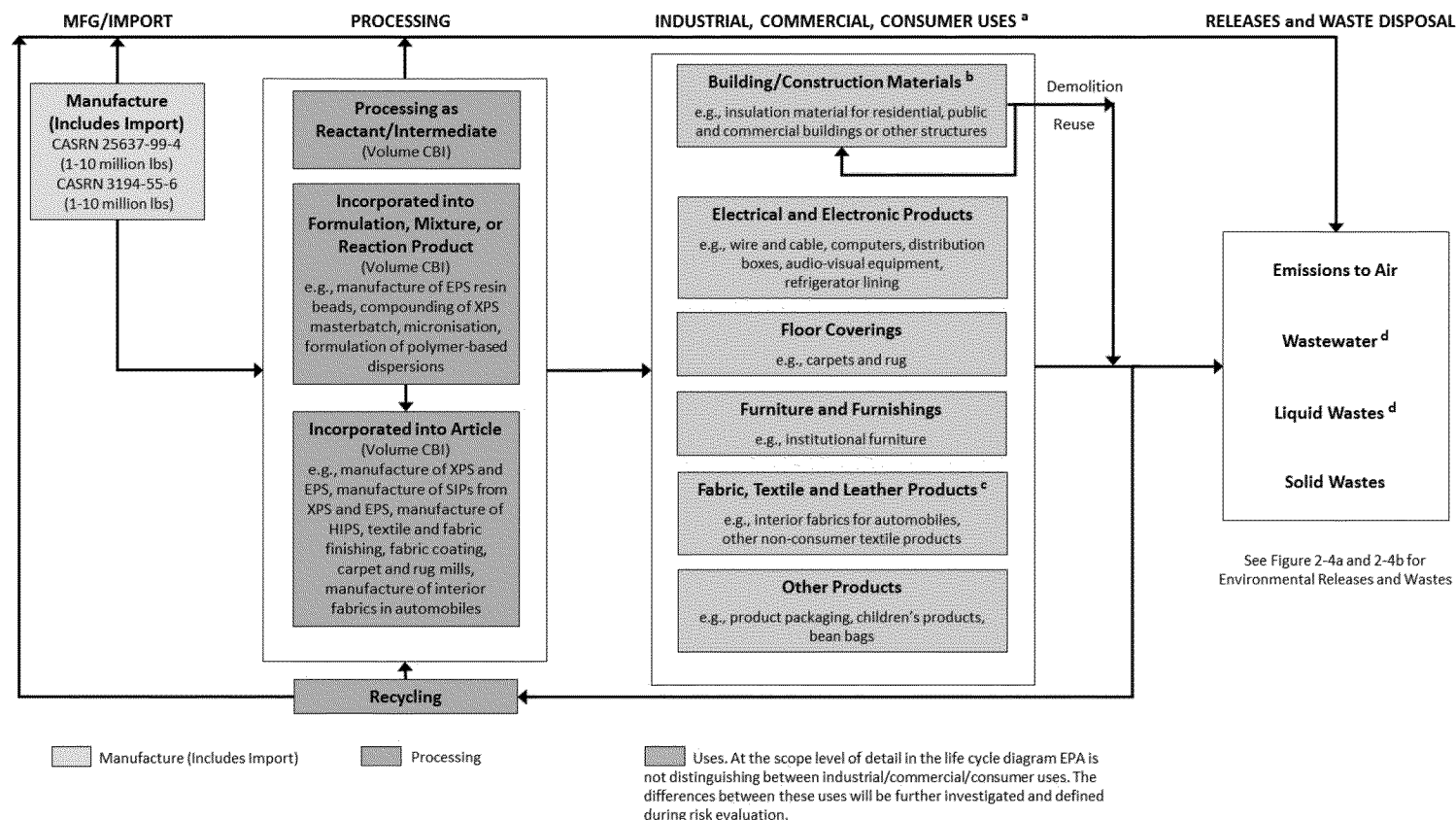


Figure 2-1. Initial HBCD Life Cycle Diagram

The initial life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period ([U.S. EPA, 2016b](#)). Activities related to distribution (e.g., loading, unloading) will be considered throughout the HBCD life cycle, rather than using a single distribution scenario. The diagram includes the major use of HBCD (insulation material for buildings or other structures) as well as reasonably foreseen uses.

^a See Table 2-3 for additional uses not mentioned specifically in this diagram. Note that insulation materials for buildings (or other structures) is confirmed as an ongoing use.

^b 2012 CDR data ([U.S. EPA, 2012b](#)) indicate that the major use of HBCD is in building and construction materials.

^c Significant New Use Rule (SNUR) ([U.S. EPA, 2015a](#)): EPA requires 90-day notification before manufacture or processing of HBCD in consumer textiles, except those used in motor vehicles.

^d Wastewater: combination of water and organic liquid, where the organic content is <50%. Liquid wastes: combination of water and organic liquid, where the organic content is >50%.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR and included in the life cycle diagram are summarized below ([U.S. EPA, 2016b](#)). The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR and can be found in EPA's [Instructions for Reporting 2016 TSCA Chemical Data Reporting](#) ([U.S. EPA, 2016a](#)).

Major Use

Expanded Polystyrene (EPS) and Extruded Polystyrene (XPS) Foam

"Building/Construction Materials" include products containing HBCD as a flame retardant primarily in XPS and EPS foam insulation products that are used for the construction of residential, public, commercial or other structures ([UNEP, 2010](#); [Weil and Levchik, 2009](#)).

Use in EPS and XPS foam accounted for 95% of all HBCD applications in the past decade ([U.S. EPA, 2013](#); [UNEP, 2010](#)). Based on information from market reports ([U.S. EPA, 2017c](#)), HBCD is used primarily in construction materials. The building and construction industry uses EPS and XPS foam in thermal insulation boards and laminates for sheathing products. EPS foam prevents freezing, provides a stable fill material and creates high-strength composites in construction applications. XPS foam board is used mainly for roofing applications and architectural molding. HBCD is used in both types of foams because it is highly effective at levels less than 1% and, therefore, maintains the insulation properties of EPS and XPS foam ([Morose, 2006](#)). EPS foam boards contain approximately 0.5% HBCD by weight in the final product and XPS foam boards contain 0.5-1% HBCD by weight (Public comment, [EPA-HQ-OPPT-2016-0735-0017](#)) ([XPSA, 2017](#); [U.S. EPA, 2014b](#); [Morose, 2006](#)).

International bans, the availability of alternatives and reported industry use statements have resulted in the use of HBCD in EPS and XPS foam declining or no longer occurring in the United States. One commenter, who represents all major North American manufacturers of EPS, reports that its members have phased out HBCD in the production of EPS resins (Public comment, [EPA-HQ-OPPT-2016-0735-0026](#)). An estimated 80-85% of EPS rigid foam insulation manufactured in the United States is supplied by EPS Industry Alliance members ([EPS Industry Alliance, 2017](#)). The status of HBCD use by non-member companies is not known. Furthermore, according to the American Chemistry Council, EPS resin manufacturers no longer have supplies of HBCD, except for importation ([Reiter, 2017](#)). Additionally, an industry association highlights that three main U.S. manufacturers of XPS have announced their intention to discontinue manufacturing HBCD ([U.S. EPA, 2017c](#)). The status of the use of HBCD in XPS foam is unknown (Public comment, [EPA-HQ-OPPT-2016-0735-0017](#)).

Reasonably Foreseen Uses

Minor uses of HBCD identified both through CDR and secondary sources are described in this section. EPA/OPPT expects to consider these uses during problem formulation.

Use in High Impact Polystyrene (HIPS)

A small amount of HBCD may also be used as a flame retardant in HIPS materials for the manufacture of products in the **“Electrical and Electronic Products”** category. It is unclear as to the amount of HBCD currently used in HIPS in the U.S.

As of 2009, in both the United States and Europe, HBCD was used as a flame retardant in HIPS for electrical and electronic appliances, such as audio-visual equipment, refrigerator lining and some wire and cable applications ([ECHA, 2009](#); [Morose, 2006](#)). Use in television sets at that time was the predominant application of HIPS ([Weil and Levchik, 2009](#)).

Use in Textiles

HBCD may have a minor application in textile coatings for the manufacture of products in the **“Fabric, Textile and Leather Products,” “Floor Coverings,”** and **“Furniture and Furnishings”** category, including interior fabrics for automobiles.

In the United States, HBCD was historically used as a flame retardant in the back coating of textiles. Information gathered from research, industry and consumer product organizations, however, has led EPA to believe that HBCD is no longer used in consumer textile applications outside of the auto industry. EPA received information from a group of textile formulators that the end uses of HBCD-containing textiles are for military, institutional and aviation applications, such as durable carpet tiles for hospitals or prisons ([U.S. EPA, 2012c](#); [Friddle, 2011](#)). Use in this application is quite small; in 2005, only 1% of HBCD was used in textiles in the United States ([U.S. EPA, 2012c](#)). EPA finalized a SNUR in 2015 ([U.S. EPA, 2015a](#)) which requires persons who intend to manufacture (including import) or process HBCD for use in consumer textiles (other than for use in motor vehicles) to notify EPA at least 90 days before commencing that activity. EPA has received no notifications since the rule became effective in late 2015, and therefore does not expect HBCD to be used in consumer textiles except as described in the SNUR. Articles containing HBCD manufactured previous to the finalization of the SNUR may continue to be in service.

EPA found that a small amount of HBCD is used in floor mats, headliners and possibly other interior fabrics in automobiles made or imported to the United States ([U.S. EPA, 2012c](#)). EPA, however, received a public comment stating that HBCD is no longer used in automobile manufacturing and is only present in replacement parts manufactured prior to date of the EPA HBCD Scoping Document (public comment, [EPA-HQ-OPPT-2016-0735-0027](#)). Conversely, a different association of automakers stated that HBCD may still be used by some non-member manufacturers in coatings of certain components, such as dashboards and headliners, in solder paste in interior components such as circuits, and in adhesives and foams (Public comment, [EPA-HQ-OPPT-2016-0735-0015](#)). A commenter reports that HBCD is not used in the manufacturing process of any automotive components and that as of 2015, members had “nearly phased out completely the use of HBCD” (Public comment, [EPA-HQ-OPPT-2016-0735-0014](#)).

Other Uses

The use of HBCD in other products is thought to be minor. In order to determine whether other uses exist and to what extent, EPA reviewed state databases, product testing results and information from foreign countries. The information is gathered in the “**other commercial and consumer use**” category. The subcategories of reasonably foreseen other uses are listed in Table 2-3.

From June 2012 to March 2017, the use of HBCD in children’s clothing, car seats, blankets, toys and toy vehicles was reported 48 times to Washington State under state law (Public comment, [EPA-HQ-OPPT-2016-0735-0022](#)). This information demonstrates that HBCD might be used in products intended for children or that HBCD is a textile contaminant and may indicate the potential for widespread human exposure to this flame retardant.

The Australian Department of Health and Aging reports that minimal amounts of HBCD are imported into Australia already incorporated into various articles, such as inkjet printers, projectors, scanners, ventilation units for offices, compact fluorescent lights and liquid-crystal display (LCD) digital audiovisual systems ([NICNAS, 2012](#)). EPA/OPPT expects to consider these uses, however, it is currently, unknown if HBCD is used in the United States for these purposes.

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of use for HBCD that EPA expects to consider in the risk evaluation. Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

Table 2-3. Categories and Subcategories of Conditions of Use for HBCD^c

Life Cycle Stage	Category ^a	Subcategory ^b	References
Manufacture	Domestic Manufacture	Domestic Manufacture	U.S. EPA (2016b)
	Import	Import	U.S. EPA (2016b)
Processing	Processing as reactant/intermediate	Intermediate for all other basic inorganic chemical manufacturing	U.S. EPA (2016b)
	Processing - incorporated into formulation, mixture or reaction product	Flame retardants used in plastic material and resin manufacturing (e.g., manufacture of EPS resin beads)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; EINECS (2008) ; Market Profile, EPA-HQ-OPPT-2016-0735
		Flame retardants used in custom compounding of purchased resin (e.g., compounding in XPS masterbatch)	EINECS (2008)

Life Cycle Stage	Category ^a	Subcategory ^b	References
		Flame retardants used in adhesive manufacturing (e.g., manufacture of solder paste and other adhesives)	Public Comment, EPA-HQ-OPPT-2016-0735-0008 ; Public Comment, EPA-HQ-OPPT-2016-0735-0015
		Flame retardants used in paints and coatings manufacturing (e.g., micronisation and formulation of polymer-based dispersions for textile coatings)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Market Profile, EPA-HQ-OPPT-2016-0735 ; EINECS (2008)
	Incorporated into article	Flame retardants used in plastics product manufacturing (manufacture of XPS and EPS foam; manufacture of structural insulated panels (SIPS) from XPS and EPS foam; manufacture of HIPS; manufacture of electronics articles)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Market Profile, EPA-HQ-OPPT-2016-0735 ; U.S. EPA (2014b)
		Flame retardants used in textiles, apparel and leather manufacturing (e.g., coatings used at textile and fabric finishing mills, fabric coating mills and carpet and rug mills)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; U.S. EPA (2014a)
		Flame retardants used in transportation equipment manufacturing (e.g., manufacture of interior components in automobiles, including fabrics, coatings, solder paste, adhesives and foams)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Market Profile, EPA-HQ-OPPT-2016-0735 ; Public Comment EPA-HQ-OPPT-2016-0735-0015

Life Cycle Stage	Category ^a	Subcategory ^b	References
	Recycling	Recycling	Use Document, EPA-HQ-OPPT-2016-0735-0003
Distribution	Distribution	Distribution	
Commercial/consumer Use	Building/construction materials	Plastic articles (hard): construction and building materials covering large surface areas (e.g., EPS/XPS foam insulation in residential, public and commercial buildings, and other structures)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; U.S. EPA (2016b) ; U.S. EPA (2014b)
	Electrical and electronic products	Plastic articles (soft) (e.g., wire and cable)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Market Profile, EPA-HQ-OPPT-2016-0735 ; U.S. EPA (2016b)
		Plastic articles (hard) (e.g., distribution boxes, audio-visual equipment; refrigerator lining; computers; Inkjet printers/scanners)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Market Profile, EPA-HQ-OPPT-2016-0735 ; U.S. EPA (2016b)
	Floor coverings	Fabrics, textiles and apparel (e.g., carpets and rugs)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ;
	Furniture and furnishings	Fabrics, textiles and apparel: Furniture and furnishings, including furniture coverings (e.g., institutional furniture)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; U.S. EPA (2015a)
	Fabric, textile and leather products ^d	Fabrics, textiles and apparel (e.g., interior fabrics for automobiles)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Market Profile, EPA-HQ-OPPT-2016-0735
		Textile finishing and impregnating/surface treatment products (e.g., other textile products)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Public Comment, EPA-HQ-

Life Cycle Stage	Category ^a	Subcategory ^b	References
			OPPT-2016-0735-0022 ; Public Comment, EPA-HQ-OPPT-2016-0735-0008
	Other uses ^e	Other (e.g., bean bags, product packaging, toys and games, car seats; children’s clothing and blankets, buoys for aquaculture, compact fluorescent lights, ventilation units for offices)	Use Document, EPA-HQ-OPPT-2016-0735-0003 ; Market Profile, EPA-HQ-OPPT-2016-0735 ; Public Comment; EPA-HQ-OPPT-2016-0735-0022 ; Public Comment, EPA-HQ-OPPT-2016-0735-0008 ; Public Comment, EPA-HQ-OPPT-2016-0735-0015
Disposal	Emissions to air	Air	EINECS (2008)
	Wastewater or liquid wastes	Industrial pre-treatment	EINECS (2008)
	Wastewater or liquid wastes	Industrial wastewater treatment	
		Publicly owned treatment works (POTW)	
		Underground injection	
		Municipal landfill	
	Waste (solid and/or liquid)	Hazardous landfill	
		Other land disposal	
		Municipal waste incinerator	
		Hazardous waste incinerator	
		Off-site waste transfer	

Note: This table presents categories and subcategories of conditions of use that are based on the 2016 CDR industrial function category and industrial sector descriptions and the OECD product and article category descriptions for the HBCD uses identified. Clarification on the subcategories of use from the listed data sources are provided in parentheses.

^a These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes and broadly represent conditions of use of HBCD in industrial and/or consumer settings.

Life Cycle Stage	Category ^a	Subcategory ^b	References
^b These subcategories reflect more specific uses of HBCD. ^c EPA assumes that the major use of HBCD is XPS and EPS foam used in building and construction materials, based on 2012 CDR data (U.S. EPA, 2016b). Other uses of HBCD not confirmed as ongoing uses may be minor or in some cases may be historical uses. ^d 2015 SNUR; (U.S. EPA, 2015a), EPA requires 90-day notification before manufacture or processing of HBCD in consumer textiles, except those used in motor vehicles. ^e Other uses in EPA's Market Report 2017 (U.S. EPA, 2017c) were identified from foreign studies and product testing results, reporting by manufacturers to the state of Washington, and other sources. For the uses in other countries, it is uncertain whether similar U.S. products contain HBCD. In some of the articles, HBCD is present but may not have been intentionally used.			

Recycling of EPS and XPS foam

To date, little is known by EPA about the recycling of products containing HBCD. [Schlummer et al.](#) notes that EPS and XPS foam in construction insulation materials are rarely recycled for numerous reasons, including that insulation waste is typically not separated from mixed waste stream and most insulation containing HBCD is still in place. ([Schlummer et al.](#)) describe technologies available only on a small scale to separate HBCD from insulation panels and recycle polystyrene.

Reuse and recycling is available in the United States for consumers through removal of insulation during re-roofing projects. Two companies were identified that directly reuse (e.g., reuse without reforming) XPS and EPS foam insulation and recycle (e.g., melting and inserting into the manufacturing process).

- Green Insulation Group: <http://www.greeninsulationgroup.com/products/>
- Nationwide Foam Recycling: <http://nationwidefoam.com/what-you-can-recycle.cfm>.

Nationwide Foam Recycling, which is owned by Conigliaro Industries, Inc., indicate that their plant recycles all EPS insulation and reuses all XPS insulation [U.S. EPA \(2017c\)](#). Once processed, their recycled EPS roofing insulation is taken to polystyrene product manufacturers, notably picture frame manufacturers, mostly in China but also in domestic markets. The company also delivers recycled roofing material to other local EPS recycling plants that may use different processes. Nationwide Foam Recycling processes 90,000 pounds/year of EPS standard packaging and 10,000 pounds/year of EPS roofing material and estimated that 10-20% of EPS roofing material is recycled nationally. The company also reuses XPS roofing material due the special equipment needed to recycle XPS and indicated that XPS is rarely recycled in the United States. It was estimated that the majority (>50%) of XPS roofing material is sent to landfills or waste energy plants. Processing estimates for XPS material were not provided.

2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to HBCD. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to HBCD.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for HBCD.

Table 2-4. Environmental Fate Characteristics of HBCD

Property or Endpoint	Value ^a	References
Direct photodegradation	Does not undergo direct photolysis (estimated)	U.S. EPA (2015b)
Indirect photodegradation	2.1 days (air)	U.S. EPA (2015b)
Hydrolysis half-life	Does not undergo hydrolysis	U.S. EPA (2015b)
Biodegradation	0% in 28 days (aerobic in wastewater, OECD 301D) 63 days (aerobic soil, OECD 307) 7 days (anaerobic soil, OECD 308) 11-32 days (aerobic sediment, OECD 308) 1.1-1.5 days (anaerobic sediment, OECD 308) 0.66 days (anaerobic in sludge)	U.S. EPA (2015b)
Bioconcentration factor (BCF)	8,974-18,100 (fish)	U.S. EPA (2015b)
Bioaccumulation factor (BAF)	3,556,000 (estimated)	U.S. EPA (2012a)
Organic carbon:water partition coefficient (log K _{oc})	4.9	U.S. EPA (2015b)
^a Measured unless otherwise noted. Based on literature review described in U.S. EPA (2015b) , Problem formulation document https://www.epa.gov/sites/production/files/2015-09/documents/hbcd_problem_formulation.pdf .		

The environmental fate of HBCD has previously been summarized in a number of other publications ([U.S. EPA, 2015b, 2014c](#); [NICNAS, 2012](#); [EC/HC, 2011](#); [EINECS, 2008](#); [U.S. EPA, 2008](#); [OECD, 2007](#)).

HBCD is persistent in environmental media. HBCD is expected to be stable to hydrolysis and direct photolysis. Measured aerobic biodegradation half-lives range from months to greater than months. Anaerobic biodegradation may be more rapid but in anaerobic conditions, degradation is also slow with half-lives ranging to months or greater. HBCD is expected to sorb to particulates and sediments and has limited mobility in soil. It is expected to have limited volatilization from soils and water surfaces. In the atmosphere, HBCD is expected to occur primarily associated with particulates and may undergo long-range transport. Particulate bound HBCD will be removed from the atmosphere by wet

or dry deposition, and has an estimated vapor-phase half-life of 2.1 days for reaction with hydroxyl radicals. HBCD is highly bioaccumulative with measured fish BCF values of 8,974-18,100.

2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

There may be releases of HBCD from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfill ([U.S. EPA, 2015b](#)). Sawing of EPS or XPS foam during commercial and consumer use results in release of HBCD to the environment and emissions of HBCD from EPS and XPS foam and wear of these products result in release of HBCD during their service life ([U.S. EPA, 2015b](#)). Disposal of EPS and XPS foam may result in releases to the environment as a result of demolition of buildings or material that is left on or in the soil ([U.S. EPA, 2015b](#)).

Articles that contain HBCD may release HBCD to the environment during use or through recycling and disposal. Examples of HBCD releases that are more recently being explored in the literature include release of HBCD from building materials through demolition ([Duan et al., 2016](#)) and sorption of suspended particles to clothing and transport down the drain during washing of textiles ([Saini et al., 2016](#)).

A source of information that EPA expects to consider in evaluating exposure are data reported under the Toxics Release Inventory (TRI) program, however, TRI data are not yet available for HBCD. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, HBCD is a TRI-reportable substance effective November 30, 2016. HBCD is reportable beginning with the 2017 calendar year and has been assigned a 100-pound reporting threshold. The first reporting forms from facilities are due by July 1, 2018.

EPA expects to consider these data in conducting the exposure assessment component of the risk evaluation for HBCD.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

Monitoring and biomonitoring data were identified in EPA's data search for HBCD.

Environment

HBCD has been widely detected in both the environment and biota. When considering monitoring studies reported in risk assessments completed to date and monitoring studies reported to open literature, there are hundreds of studies that have reported HBCD in various media (see Systematic Review Appendix; ([NICNAS, 2012](#); [EC/HC, 2011](#); [EINECS, 2008](#)).

HBCD has been detected in a wide variety of environmental media. Based on review of previously completed assessments and EPA's problem formulation ([U.S. EPA, 2015b](#)), HBCD is expected to be

present at relatively higher levels in sediment, soil and indoor dust. HBCD is also expected to be present in ambient air, indoor air and surface water at relatively lower levels. Physical-chemical properties influence the fate and transport of HBCD between media. For example, EPA expects to consider partitioning of HBCD to sediment within the water column and to suspended particles and dust in indoor environments ([Law et al., 2014](#)). HBCD has also been detected in remote areas and in very close proximity to industrial sources and many sampling locations in between ([Law et al., 2014](#)). EPA expects to consider and review readily available environmental monitoring data in the risk evaluation.

Biota

HBCD has the potential to both persist and bioaccumulate in the environment ([UNEP, 2010](#)). Once HBCD is present in the environment, it is available for uptake by a variety of species, including humans. HBCD has been detected in human milk, adipose tissue, blood and hair. HBCD has been detected in invertebrates, fish, birds, mammals and plants. HBCD is also present in edible fish, plants, milk and other food sources, and there are existing studies that quantify potential dietary exposures ([NICNAS, 2012](#); [EC/HC, 2011](#); [EINECS, 2008](#)). EPA expects to consider and review readily available biomonitoring data in the risk evaluation.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of HBCD can result in releases the environment. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-4a and Figure 2-4b in conducting the risk evaluation for HBCD.

2.3.5 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

EPA anticipates inhalation of dust and other respirable particles (for example, resulting from particulate generated by hot wire cutting of EPS or XPS foam) as the most important HBCD exposure pathway for workers and occupational non-users ([U.S. EPA, 2015b](#); [NICNAS, 2012](#); [ECHA, 2009](#); [EINECS, 2008](#)); however, dermal exposure, including skin contact with liquids and solids, may also occur when performing certain work activities.

Workers and occupational non-users may be exposed to HBCD when performing activities associated with the conditions of use described in Section 2.2, including, but not limited to:

- Loading and transferring HBCD powder from process vessels to sacks or bags.
- Applying formulations containing HBCD onto substrates (e.g., textile coatings).

- Handling, transporting and disposing waste containing HBCD.
- Performing other work activities in or near areas where HBCD is used.
- Cutting EPS or XPS foam (e.g., at construction sites).

Based on these activities, EPA expects to consider inhalation exposure to particulates and dermal exposure, including skin contact with particulates for workers and occupational non-users. EPA also expects to consider potential worker exposure via the oral route such as from incidental ingestion of HBCD residue on hand/body or through particulates that deposit in the upper respiratory tract.

Occupational exposure limits for HBCD have not been established by the Occupational Safety and Health Administration (OSHA), the American Conference of Government Industrial Hygienists (ACGIH), or the National Institute of Occupational Safety and Health (NIOSH).

<https://www.ncbi.nlm.nih.gov/books/NBK225635/>

2.3.5.2 Consumer Exposures

HBCD may be found in consumer products and articles and/or commercial products and articles that are available for public purchase at common retailers ([EPA-HQ-OPPT-2016-0735-0003](#), Sections 3 and 4, ([U.S. EPA, 2017b](#))) and can therefore result in exposures to consumers.

Exposure routes for consumers using HBCD-containing products may include inhalation of particulates or emitted vapor, dermal exposure due to contact with articles and ingestion of settled dust and mouthing of articles.

Consumer exposure to articles containing HBCD is somewhat different from consumer exposure to a product where the chemical is consumed during its use and then discarded (for example, a can of spray paint). HBCD is incorporated into articles that may be present during the entire useful life of the article in microenvironments where consumers may be continually exposed until disposal of the article. HBCD-containing articles (e.g., insulation, electronics products, plastic based products and textiles) have relatively long service lives in comparison to other consumer products that are quickly used and discarded. Indoor environments with elevated levels of HBCD in indoor air and dust may contain some combination of articles containing HBCD.

Consumer exposure to HBCD may include inhalation exposure related to emissions of HBCD from articles. Indoor air concentrations may vary by infiltration from ambient air or emissions associated with presence of articles. Emission from articles will vary based on the surface area of the article present in the building, the weight fraction of HBCD and building characteristics such as air exchange and inter-zonal air flow. Based on the relatively high octanol:air partition coefficient (K_{oa}) and relatively low vapor pressure, HBCD emitted to indoor air is likely to partition to suspended particles and potentially settle to dust rather than be emitted in its vapor phase.

Consumer exposure to HBCD may include oral exposure related to mouthing of articles and objects containing HBCD. Exposures related to the mouthing of objects are influenced by the migration rate of the chemical from the material into saliva, the duration of contact time for mouthing, and the prevalence/likelihood of the article being mouthed. EPA expects to consider these factors in developing exposure estimates from mouthing.

Consumer exposure to HBCD may include dermal exposure related to direct skin contact with articles containing HBCD. However, there are several factors to be considered and this is likely a relatively minor pathway compared to dermal contact with dust. The contact duration, solubility and diffusivity of HBCD within different articles, and contact surface area of skin all influence potential exposures (EINECS, 2008).

There may be some consumers who may have greater exposure potential to HBCD such as:

- Children or adults who spend time in microenvironments with elevated dust or indoor air concentrations due to presence of multiple article which contain elevated levels of HBCD.
- Children or adults who have elevated contact time, due to mouthing and/or dermal contact, with multiple articles containing HBCD.

EPA expects to consider inhalation, dermal and oral exposures to consumers and bystanders associated with the consumer use in the home.

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of HBCD could result in potential pathways for oral, dermal or inhalation exposure to the general population. EPA expects to consider each media, route and pathway to estimate general population exposures.

Inhalation

There is the potential for inhalation exposure to HBCD by breathing ambient air and indoor air. Ambient air concentrations may vary by proximity to an industrial source, while indoor air concentrations are discussed in the consumer exposure section. Based on the relatively high K_{oa} and relatively low vapor pressure, HBCD is expected to be present primarily in suspended particles in the air rather than in the vapor phase.

Based on these potential sources and pathways of exposure, EPA expects to consider inhalation exposures of the general population to air/particulates containing HBCD that may result from the conditions of use of HBCD.

Oral

The general population may ingest HBCD via a variety of exposure pathways.

There is potential for oral exposure to HBCD by ingestion of dust and soil; drinking water and breast milk; and edible aquatic and terrestrial biota (e.g., from fishing, hunting, gathering and farming). There is a wide range of dust and soil monitoring data available. Dust concentrations vary widely across different microenvironments and within microenvironments and are generally reported in the ng/g or µg/g range (U.S. EPA, 2015b). Existing exposure assessments outside of the United States have quantified dietary exposure from a variety of food sources and compared these values to other pathways (EC/HC, 2011; EINECS, 2008). Exposures from drinking water containing HBCD are possible, but are likely to be relatively lower than other oral exposure pathways (EC/HC, 2011; EINECS, 2008).

Based on these potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the conditions of use of HBCD.

Dermal

There is potential for dermal exposure to HBCD through contact with dust and soil containing HBCD. Dermal exposure is likely to vary based on the contact time with the material, the concentration of HBCD and properties of HBCD that influence the chance of dermal absorption (EINECS, 2008).

Based on these potential sources and pathways of exposure, EPA expects to consider dermal exposures to the general population that may result from the conditions of use of HBCD.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to “a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation” by EPA. TSCA § 3(12) states that “the term ‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.”

In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure*, that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. HBCD has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or disposal sites).

There are some reasonably likely exposure scenarios where greater exposure from multiple sources may occur. There may be some individuals who have greater potential for exposure to HBCD such as:

- Children who spend time in microenvironments with elevated dust concentrations.
- Breast-fed infants where concentrations of breast milk containing HBCD are elevated.
- Children or adults who ingest soil or sediment in environments where HBCD concentrations are elevated.
- Adults who have elevated intake rates of edible aquatic biota or terrestrial biota containing elevated levels of HBCD.

In developing scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or lifestage (e.g., children’s crawling, mouthing or hand-to-mouth behaviors) and whether some human

receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population ([U.S. EPA, 2006](#)).

In summary, in the risk evaluation for HBCD, EPA expects to consider the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of HBCD, as described in *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0735](#)). Based on initial screening, EPA expects to consider the hazards of HBCD identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for HBCD: [U.S. EPA \(2016c\)](#); [U.S. EPA \(2014d\)](#); [NICNAS \(2012\)](#); [EC/HC \(2011\)](#); [UNEP \(2010\)](#); [U.S. EPA \(2010\)](#); [EINECS \(2008\)](#); [OECD \(2007\)](#). However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for HBCD [*HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0735*].

EPA expects to consider the hazards of HBCD to aquatic organisms including fish, aquatic invertebrates, aquatic plants and sediment invertebrates exposed to relevant media under acute and chronic exposure conditions. Based on the assessments mentioned above, there was acute toxicity to aquatic invertebrates from HBCD, based on mortality and immobilization. Chronic toxicity to aquatic invertebrates (growth and reproduction) was observed when exposed to HBCD. Chronic toxicity was observed in sediment dwelling organisms based on reduced survivability when exposed to HBCD.

EPA expects to consider the hazards of HBCD to terrestrial organisms including soil invertebrates and avian species exposed to relevant media under acute and chronic exposure conditions. Based on previous assessments, chronic toxicity to terrestrial invertebrates (reproduction) was observed when exposed to HBCD. Also, toxicity to avian species was observed, based on reduced hatchability and survival, when exposed to HBCD.

2.4.2 Human Health Hazards

The human health hazard of HBCD has been examined in several publications ([U.S. EPA, 2016c, 2014b, d](#); [NICNAS, 2012](#); [EC/HC, 2011](#); [EINECS, 2008](#); [U.S. EPA, 2008](#); [OECD, 2007](#)).

HBCD does not have an existing EPA IRIS Assessment; however, as part of a coordinated agency effort, the TRI Technical Review of HBCD ([U.S. EPA, 2016c](#)), 2015 HBCD Problem Formulation and Initial

Assessment (PFIA) ([U.S. EPA, 2015b](#)), and *Preliminary Materials for the IRIS Toxicological Review of HBCD* ([U.S. EPA, 2014d](#)) compiled and reviewed non-cancer health hazards of HBCD, including: acute toxicity, liver toxicity, thyroid toxicity, reproductive/developmental toxicity, neurotoxicity, immunotoxicity, sensitization and irritation. EPA has relied heavily on this comprehensive review in preparing this scope. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since this review, as identified in the literature search conducted by the Agency for HBCD [*HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0735*]. EPA expects to consider all potential hazards associated with HBCD. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

2.4.2.1 Non-Cancer Hazards

Acute Toxicity

Animal studies have observed potential neurological effects and clinical signs of toxicity including death following high-dose acute administration of HBCD ([U.S. EPA, 2015b](#)).

Liver Toxicity

Increased liver weight has been observed in multiple laboratory animal studies, in both sexes, across species and following both adult and developmental exposures. In mice, HBCD exposure induced evidence of inflammatory changes in the liver and hepatic fatty changes (steatosis) in animals with a high-fat diet ([U.S. EPA, 2014d](#)).

Thyroid Toxicity

Human epidemiological studies have reported potential effects of HBCD on thyroid hormones. Animal toxicity studies provide stronger evidence of thyroid perturbation associated with HBCD exposure, including altered levels of thyroid hormones, histological changes and increased thyroid weight, with effects observed across multiple lifestages, sexes, species and exposure durations ([U.S. EPA, 2014d](#)).

Reproductive/Developmental Toxicity

For female reproductive effects, there is some rodent evidence that HBCD may alter fertility and pregnancy outcomes as well as reduce the number of mature and developing follicles in the ovary; however, effects on reproductive organ weight are inconsistent. For male reproductive effects, there is some epidemiological support of an association between HBCD exposure and altered serum testosterone and sex hormone binding globulin (SHBG) levels; however, animal studies did not report any effects on male reproductive organ weights, reproductive development, hormone concentrations or spermatogenic measures. There is mixed epidemiological data on developmental toxicity of HBCD, while animal toxicity studies suggest that early life exposure to HBCD at high doses can affect various developmental outcomes, including reduced offspring viability, decrements in pup weight and alterations in eye opening ([U.S. EPA, 2014d](#)).

Neurotoxicity

There is an absence of a strong association in epidemiological studies between HBCD exposure and developmental neurotoxicity in various neuropsychological domains; however, there is evidence of potential developmental neurotoxicity in rodents. Perinatal HBCD exposure was shown to alter neurodevelopmental milestones while eliciting changes in locomotor activity and executive function

that persisted into adulthood. HBCD exposure also appears to affect other neurological endpoints related to changes in auditory sensitivity, dopamine system function and brain weight in multiple studies. Effects on neurodevelopmental endpoints were observed in both sexes and across a wide range of doses and exposure durations. However, there is currently not any substantial evidence to support concern for neurotoxicity during when exposure is limited to adulthood ([U.S. EPA, 2014d](#)).

Immunotoxicity

The effects of HBCD on both functional and structural immune endpoints have been evaluated in animal models. Overall, immunological effects from HBCD exposure are variable and inconsistent across studies for endpoints such as immune organ weights, hematology or histopathology ([U.S. EPA, 2014d](#)), and its relevance to the risk evaluation will require further evaluation.

Sensitization/Irritation

There is limited information available suggesting potential mild irritation and sensitizing potential of HBCD ([U.S. EPA, 2015b](#)).

2.4.2.2 Genotoxicity and Cancer Hazards

Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic ([NICNAS, 2012](#); [EINECS, 2008](#); [TemaNord, 2008](#); [OECD, 2007](#)).

Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time. Consistent with the discussion in the preamble to the risk evaluation rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, pertaining to conditions of use, EPA does not believe it makes sense to expend Agency resources evaluating hazards that EPA is confident are not presented by a chemical substance.

2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to “a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation” by EPA. TSCA § 3(12) states that “the term ‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” In developing the hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical’s hazard(s).

2.5 Initial Conceptual Models

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for HBCD, EPA developed three conceptual models, presented here.

2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial uses of HBCD. EPA expects that workers and occupational non-users may be exposed to HBCD via inhalation, dermal and oral routes. EPA anticipates inhalation of dust containing HBCD to be an important exposure route (U.S. EPA, 2015b). Dermal exposure may occur as a result of handling HBCD in certain conditions of use such as formulation of polymer dispersions or handling of particulate solids (OECD, 2015; EINECS, 2008). Oral exposure of workers to HBCD may occur through ingestion of dust that deposits in the upper respiratory tract and is swallowed or via incidental ingestion of HBCD following hand and body contact.

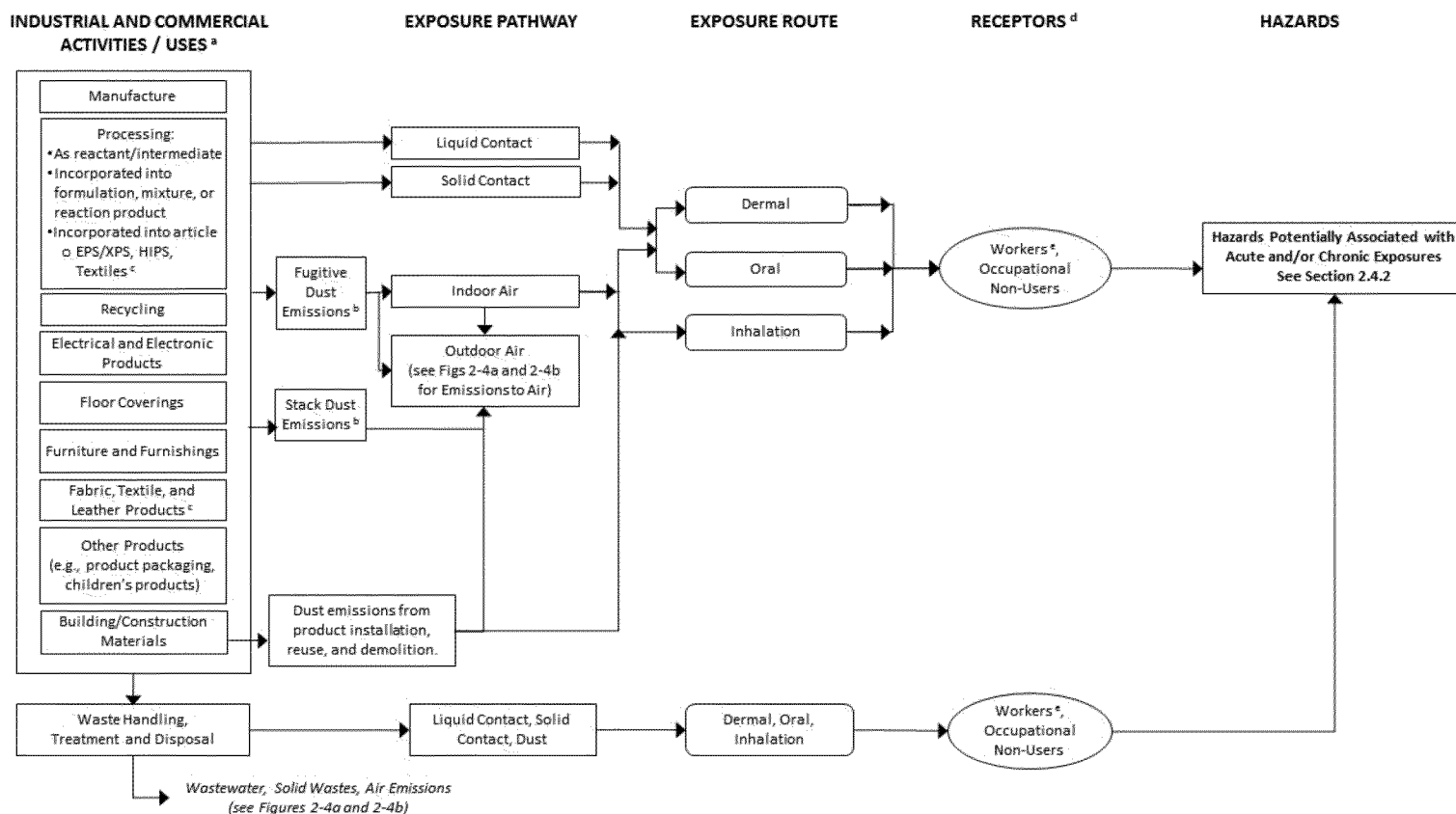


Figure 2-2. Initial HBCD Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of HBCD.

^a Some products are used in both commercial and consumer applications. Additional uses of HBCD are included in Table 2-3.

^b Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions, and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

^c SNUR: EPA requires 90-day notification before manufacture or processing of HBCD in consumer textiles, except those used in motor vehicles.

^d Receptors include potentially exposed or susceptible subpopulations.

^e When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-3 presents the initial conceptual model for human receptors from consumer uses of HBCD. EPA expects that consumers and bystanders may be exposed via inhalation related to emissions of HBCD from articles, oral exposure related to mouthing of articles and objects containing HBCD and incidental ingestion of settled dust containing HBCD. Exposure to HBCD may also potentially include dermal exposure related to direct skin contact with articles containing HBCD. It should be noted that some consumers may purchase and use products primarily intended for commercial use.

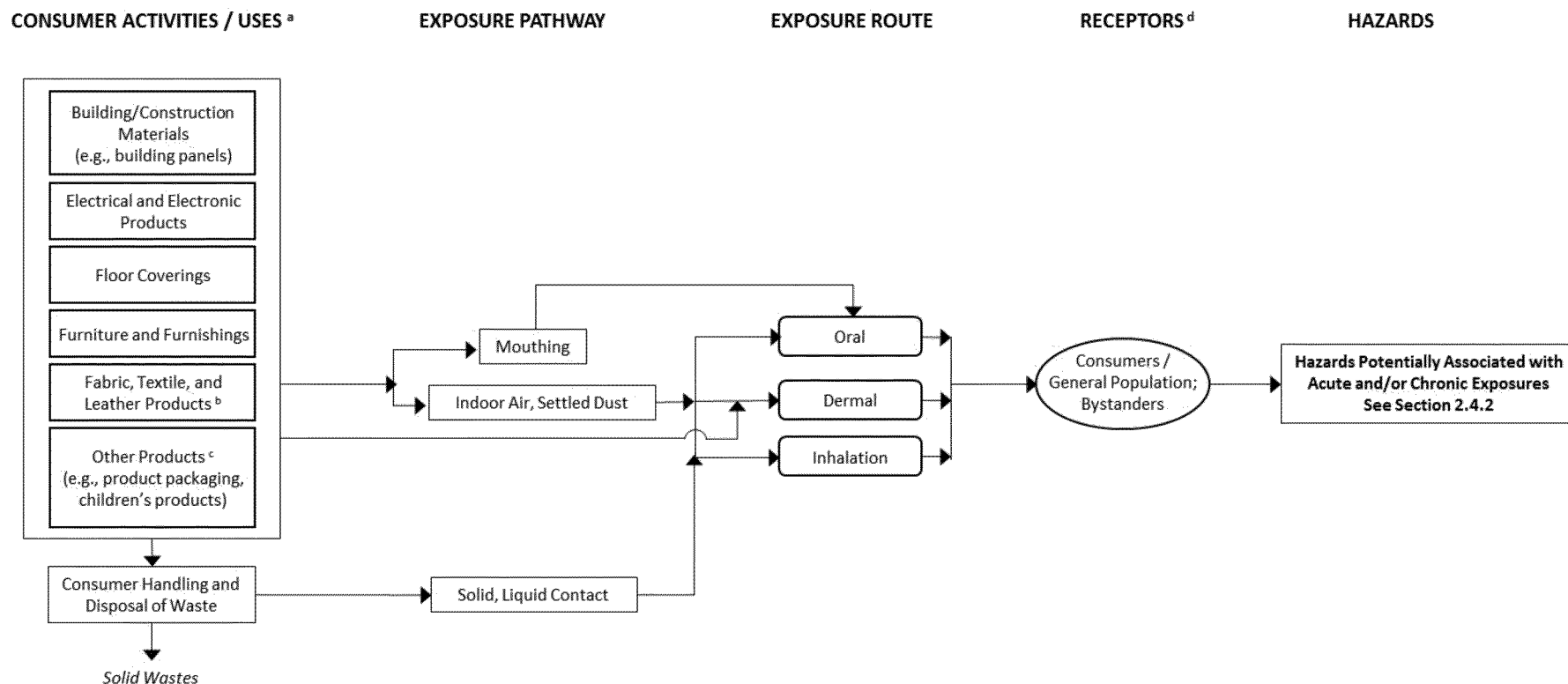


Figure 2-3. Initial HBCD Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of HBCD.

^a Some products are used in both commercial and consumer applications. Additional uses of HBCD are included in Table 2-3.

^b SNUR: EPA requires 90-day notification before manufacture or processing of HBCD in consumer textiles, except those used in motor vehicles.

^c Prevalence of use is unknown; some data are from product testing.

^d Receptors include potentially exposed or susceptible subpopulations.

2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

As shown in Figure 2-4a, EPA anticipates that the general population living near industrial and commercial facilities using or disposing of HBCD may be exposed via several pathways. As HBCD is persistent and bioaccumulative, releases to air, water or land from industrial or commercial activities are expected to result in exposures to human receptors via ingestion of water, breast milk and edible aquatic and terrestrial biota (e.g., from fishing, hunting, gathering, farming). Inhalation may also be anticipated for the general population if releases to air occur, although the exposure may vary depending upon the proximity to the industrial source. Dermal routes of exposure are also possible.

Releases of HBCD to air, water or land from industrial or commercial activities may result in exposure to aquatic and terrestrial life via contaminated water, sediment or soil as shown in Figure 2-4b.

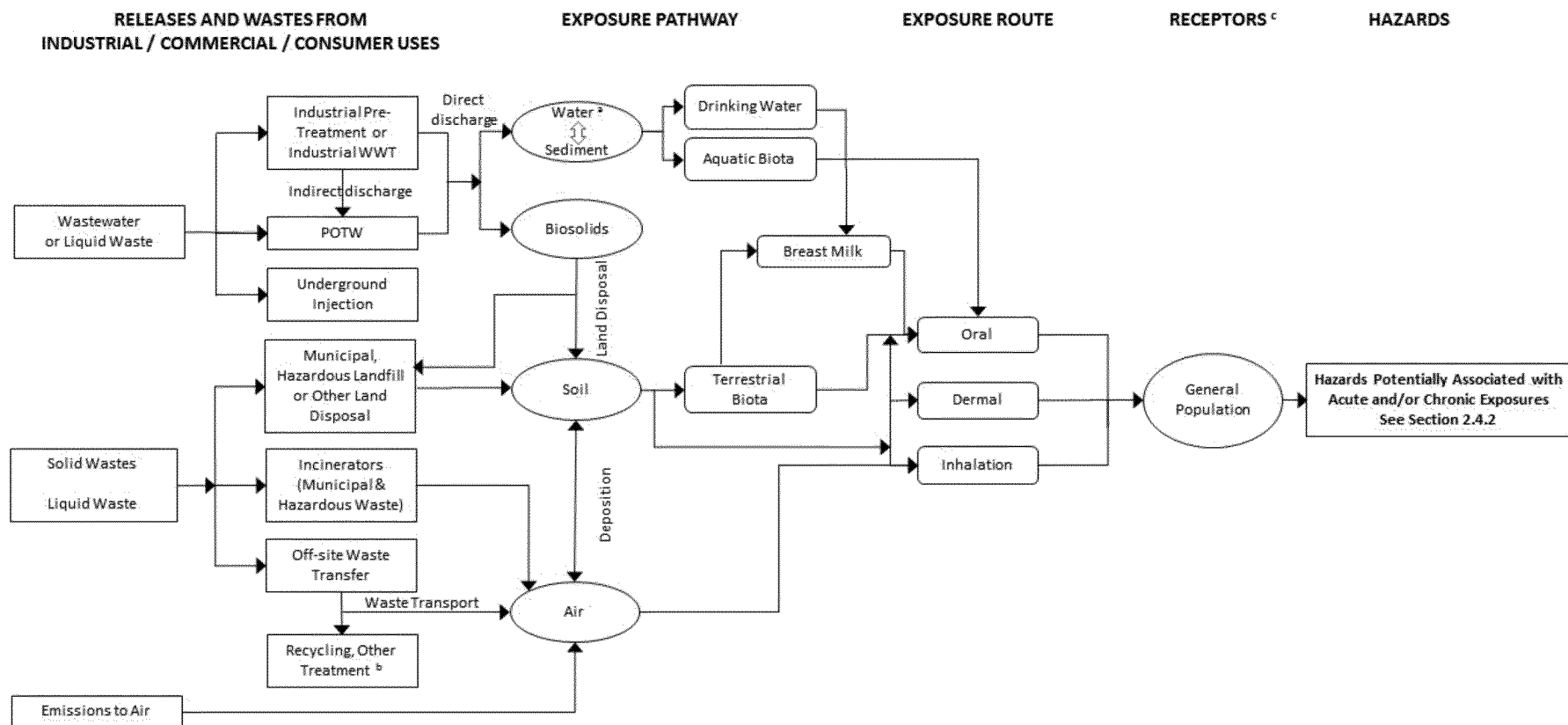


Figure 2-4a. Initial HBCD Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial and commercial uses of HBCD.

^a Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

^b Additional releases may occur from recycling and other waste treatment.

^c Receptors include potentially exposed or susceptible subpopulations.

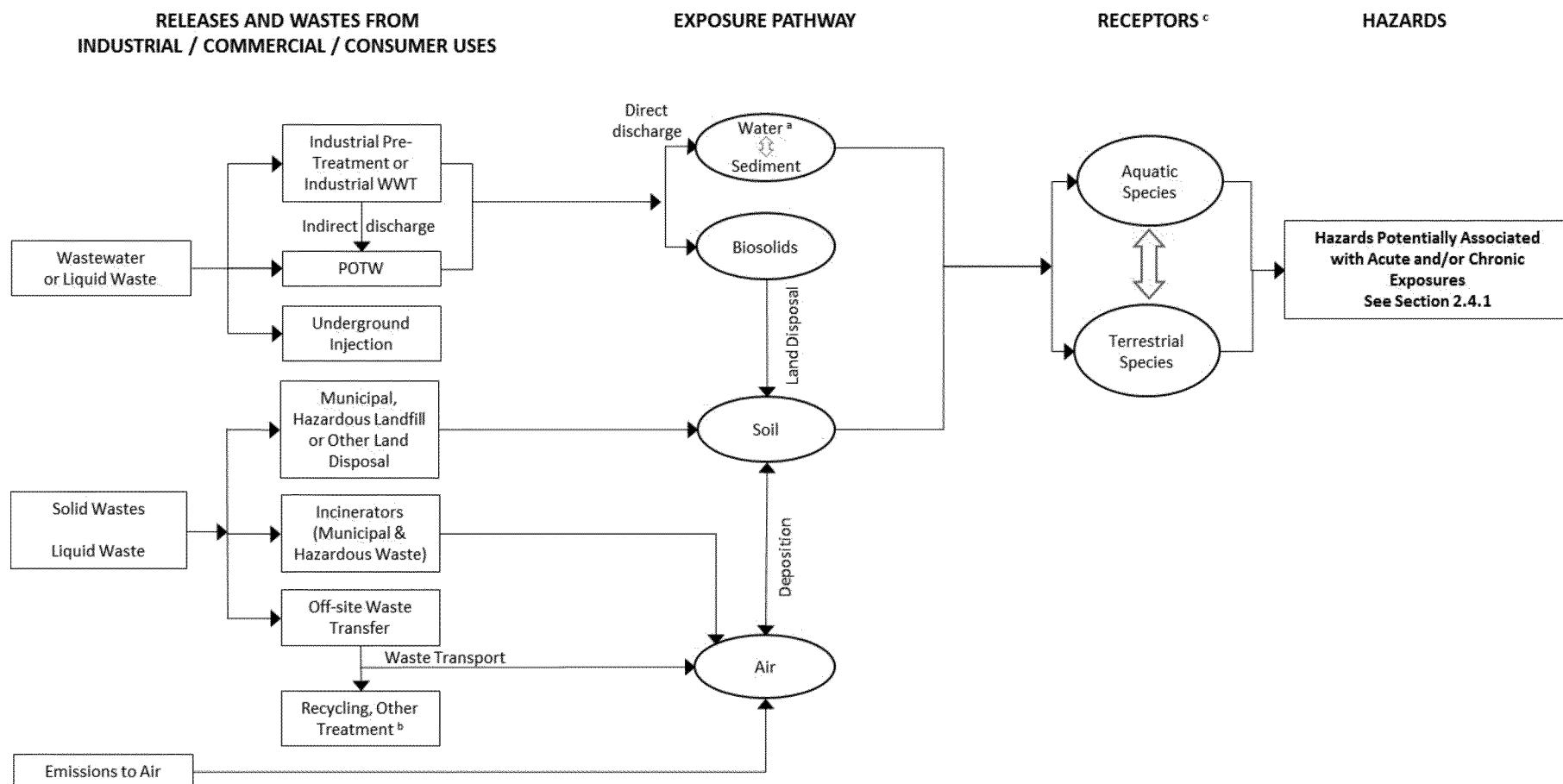


Figure 2-4b. Initial HBCD Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways and hazards for environmental receptors from industrial and commercial uses of HBCD.

^a Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

^b Additional releases may occur from recycling and other waste treatment.

^c Receptors include potentially exposed or susceptible subpopulations.

2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources as described in Section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of HBCD, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, ([EPA-HQ-OPPT-2016-0735](#)). EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

2.6.1 Exposure

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to environmental media as follows:

- 1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated.
- 2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI and National Emissions Inventory [NEI] programs).
- 3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
- 4) Understand and consider regulatory limits that may inform estimation of environmental releases.
- 5) Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.
- 6) Evaluate the weight of the evidence of environmental release data.
- 7) Map or group each condition(s) of use to a release assessment scenario.

2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

- 1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.
- 2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.
- 3) Evaluate the weight of the evidence of environmental fate data.

2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its environmental exposure assessment of HBCD:

- 1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
- 2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
- 3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- 4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to extent data are available, and characterize exposed aquatic and terrestrial populations.
- 5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
- 6) Map or group each condition(s) of use to environmental assessment scenario(s).

2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

- 1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements)).
- 2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to HBCD.
- 3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
- 5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
- 6) Evaluate the weight of the evidence of occupational exposure data.
- 7) Map or group each condition of use to occupational exposure assessment scenario(s).

2.6.1.5 Consumer Exposures

EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

- 1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures.
- 2) Evaluate the weight of the evidence of consumer exposure data.
- 3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.

- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
- 5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
- 6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
- 7) Map or group each condition of use to consumer exposure assessment scenario(s).

2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

- 1) Review available environmental and biological monitoring data for media to which general population exposures are expected. For exposure pathways where data is not available, review existing exposure models that may be applicable in estimating exposure levels.
- 2) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
- 3) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
- 4) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
- 5) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further defined.
- 6) Evaluate the weight of the evidence of general population exposure data.
- 7) Map or group each condition of use to general population exposure assessment scenario(s).

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA will conduct an environmental hazard assessment of HBCD as follows:

- 1) Review available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
- 2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
- 3) Derive concentrations of concern (COC) for all identified ecological endpoints.
- 4) Evaluate the weight of the evidence of environmental hazard data.
- 5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

- 1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
- 2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
- 3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.
- 4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
- 5) Evaluate the weight of the evidence of human health hazard data.
- 6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) (U.S. EPA, 2000). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

REFERENCES

- Albemarle (Albemarle Corporation). (2000). Saytex HP-900 flame retardant [Fact Sheet]. Baton Rouge, LA.
http://www.albemarle.com/filelib/FileCabinet/Products/Fire_Safety/SAYTEX_PURshield_online.pdf
- Borchardt, JK. (2006). Recycling, plastics. In Kirk-Othmer Encyclopedia of Chemical Technology (5th ed.). New York: John Wiley & Sons.
- CPSC (U.S. Consumer Product Safety Commission). (2001). CPSC staff exposure and risk assessment of flame retardant chemicals in residential upholstered furniture. Bethesda, MD.
<http://dx.doi.org/10.13140/RG.2.1.3291.6646>
- Duan, H; Yu, D; Zuo, J; Yang, B; Zhang, Y; Niu, Y. (2016). Characterization of brominated flame retardants in construction and demolition waste components: HBCD and PBDEs. *Sci Total Environ* 572: 77-85. <http://dx.doi.org/10.1016/j.scitotenv.2016.07.165>
- EC/HC (Environment Canada and Health Canada). (2011). Screening assessment report on hexabromocyclododecane. Chemical Abstracts Service Registry Number 3194-55-6. Ottawa, Canada. <https://www.ec.gc.ca/ese-ees/7882C148-8AE4-4BA4-8555-668C49F91500/HBCD%20-%20FSAR%20-%20EN.pdf>
- ECHA (European Chemicals Agency). (2009). Data on manufacture, import, export, uses and releases of HBCDD as well as information on potential alternatives to its use. In IOM Consulting, supported by BRE, PFA and Entec (pp. 108). (ECHA/2008/2). Helsinki, Finland.
https://echa.europa.eu/documents/10162/13640/tech_rep_hbcd_en.pdf
- EINECS. (2008). Risk assessment: Hexabromocyclododecane. Cas-No.: 25637-99-4. Luxembourg: European Inventory of Existing Commercial Chemical Substances, Office for Official Publications of the European Communities. <https://echa.europa.eu/documents/10162/661bff17dc0a-4475-9758-40bdd6198f82>
- EPS Industry Alliance. (2017). Preliminary information on manufacturing, processing, distribution, use, and disposal: Cyclic aliphatic bromide cluster (HBCD). OCSPP. Public comment. (EPA-HQ-OPPT-2016-0735-0026).
- Friddle, J. (2011). Use of HBCD in Textiles. Calhoun, GA.: Eagle Performance Products.
- Law, RJ; Covaci, A; Harrad, S; Herzke, D; Abdallah, MA; Fernie, K; Toms, LM; Takigami, H. (2014). Levels and trends of PBDEs and HBCDs in the global environment: status at the end of 2012 [Review]. *Environ Int* 65: 147-158. <http://dx.doi.org/10.1016/j.envint.2014.01.006>
- Morose, G. (2006). An overview of alternatives to tetrabromobisphenol A (TBBPA) and hexabromocyclododecane (HBCD). In Lowell Center for Sustainable Production, University of Massachusetts, Lowell (pp. 1-32). Lowell, MA.: Prepared for the Jennifer Altman Foundation.
<http://www.chemicalspolicy.org/downloads/AlternativestoTBBPAandHBCD.pdf>
- NICNAS (National Industrial Chemicals Notification and Assessment Scheme). (2012). Hexabromocyclododecane: Priority existing chemical assessment report no. 34. Australia.
http://www.nicnas.gov.au/Publications/CAR/PEC/PEC34/HBCD_Report_June_2012_PDF.pdf
- OECD (Organisation for Economic Co-operation and Development). (2004). Emission scenario document on textile finishing. (Number 7). Paris, France.
- OECD (Organisation for Economic Co-operation and Development). (2007). SIDS Initial Assessment Profile for HBCDD. In OECD Existing Chemicals Database (pp. 1-4). Paris, France.
<http://webnet.oecd.org/HPV/UI/handler.axd?id=ea58ac11e090-4b24-b281-200ae351686c>
- OECD (Organisation for Economic Co-operation and Development). (2015). Emission scenario document on use of adhesives. (Number 34). Paris, France.

- [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO\(2015\)4&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2015)4&doclanguage=en)
- Priddy, DB. (2006). Styrene plastics. In Kirk-Othmer Encyclopedia of Chemical Technology (5th ed.). New York: John Wiley & Sons.
- Reiter, W. (2017). Notes from EPA meeting with American Chemistry Council on HBCD use. Washington, DC: Reiter, W.
- Saini, A; Thaysen, C; Jantunen, L; Mcqueen, RH; Diamond, ML. (2016). From clothing to laundry water: investigating the fate of phthalates, brominated flame retardants, and organophosphate esters. Environ Sci Technol 50: 9289-9297. <http://dx.doi.org/10.1021/acs.est.6b02038>
- Schlummer, M; Maurer, A; Wagner, S; Berrang, A; Siebert, T; Knappich, F. (2017). Recycling of flame retarded waste polystyrene foams (EPS and XPS) to PS granules free of hexabromocyclododecane (HBCDD). Schlummer, M; Maurer, A; Wagner, S; Berrang, A; Siebert, T; Knappich, F. http://www.synbratetechnology.com/media/11693/fraunhoferwebsite_creasolv_processing-of-hbcd-containing-polystyrene-from-construction-eps-1.pdf
- Suh, KW. (2000). Foamed plastics [Encyclopedia]. In Kirk-Othmer Encyclopedia of Chemical Technology. Hoboken, NJ: John Wiley and Sons, Inc. <http://dx.doi.org/10.1002/0471238961.06150113192108.a01>
- TemaNord. (2008). Hexabromocyclododecane as a possible global POP. [online]: Nordic Council of Ministers.
- U.S. EPA (U.S. Environmental Protection Agency). (2000). Science policy council handbook: Risk characterization (pp. 1-189). (EPA/100/B-00/002). Washington, D.C.: U.S. Environmental Protection Agency, Science Policy Council. <https://www.epa.gov/risk/risk-characterization-handbook>
- U.S. EPA (U.S. Environmental Protection Agency). (2006). A framework for assessing health risk of environmental exposures to children (pp. 1-145). (EPA/600/R-05/093F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363>
- U.S. EPA (U.S. Environmental Protection Agency). (2008). Initial risk-based prioritization of high production volume chemicals: Chemical/category: Hexabromocyclododecane (HBCD) CAS 3194-55-6 1,2,5,6,9,10 hexabromocyclododecane CAS 25637-99-4 hexabromocyclododecane. Washington, DC.
- U.S. EPA (U.S. Environmental Protection Agency). (2010). Hexabromocyclododecane (HBCD) action plan summary [EPA Report]. Washington, D.C. <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/hexabromocyclododecane-hbcd-action-plan>
- U.S. EPA (U.S. Environmental Protection Agency). (2012a). Estimation Programs Interface Suite for Microsoft Windows, v 4.11 [Computer Program]. Washington, DC. Retrieved from <https://www.epa.gov/tsca-screening-tools/epi-suite-tm-estimation-program-interface>
- U.S. EPA (U.S. Environmental Protection Agency). (2012b). Non-confidential 2012 Chemical Data Reporting (CDR) Database. Available online at <http://www.epa.gov/cdr/>
- U.S. EPA (U.S. Environmental Protection Agency). (2012c). Significant new use rule for hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane. Fed Reg 77: 17386-17394.
- U.S. EPA (U.S. Environmental Protection Agency). (2013). ChemSTEER User Guide - Chemical Screening Tool for Exposures and Environmental Releases. Environmental Protection Agency. https://www.epa.gov/sites/production/files/2015-05/documents/user_guide.pdf

- U.S. EPA (U.S. Environmental Protection Agency). (2014a). Economic analysis of the proposed rule to add HBCD to the list of TRI reportable chemicals (pp. 57). (In Docket EPA-HQ-TRI-2015-0607-0029.). Washington DC: U. S. Environmental Protection Agency.
<https://www.regulations.gov/#!documentDetail;D=EPA-HQ-TRI-2015-0607-0029>
- U.S. EPA (U.S. Environmental Protection Agency). (2014b). Flame retardant alternatives for hexabromocyclododecane (HBCD) [EPA Report]. (EPA/740/R-14/001). Washington, D.C.
<http://www2.epa.gov/saferchoice/partnershipevaluate-flame-retardant-alternatives-hbcd-publications>
- U.S. EPA (U.S. Environmental Protection Agency). (2014c). Framework for human health risk assessment to inform decision making. Final [EPA Report]. (EPA/100/R-14/001). Washington, DC: U.S. Environmental Protection, Risk Assessment Forum.
<http://www2.epa.gov/risk/framework-human-health-risk-assessment-inform-decision-making>
- U.S. EPA (U.S. Environmental Protection Agency). (2014d). Preliminary materials for the Integrated Risk Information System (IRIS) Toxicological review of hexabromocyclododecane (HBCD). In National Center for Environmental Assessment, Office of Research and Development (pp. 84). (EPA/630/R-13/235). Washington, DC: U.S. Environmental Protection Agency.
https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=521738
- U.S. EPA (U.S. Environmental Protection Agency). (2015a). Comments from the significant new use rules: Hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane. Fed Reg 80: 57293-57302.
- U.S. EPA (U.S. Environmental Protection Agency). (2015b). TSCA Work Plan chemical problem formulation and initial assessment. Cyclic aliphatic bromide cluster flame retardants. In Office of Chemical Safety and Pollution Prevention. (EPA 743-D1-5001). Washington, DC.
https://www.epa.gov/sites/production/files/2015-09/documents/hbcd_problem_formulation.pdf
- U.S. EPA (U.S. Environmental Protection Agency). (2016a). Instructions for reporting 2016 TSCA chemical data reporting. <https://www.epa.gov/chemical-data-reporting/instructions-reporting-2016-tsca-chemical-data-reporting>
- U.S. EPA (U.S. Environmental Protection Agency). (2016b). Public database 2016 chemical data reporting (May 2017 release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from <https://www.epa.gov/chemical-data-reporting>
- U.S. EPA (U.S. Environmental Protection Agency). (2016c). Technical review of hexabromocyclododecane (HBCD) CAS registry numbers 3194-55-6 and 25637-99-4. Washington, DC: U. S. Environmental Protection Agency.
<https://www.regulations.gov/document?D=EPA-HQ-TRI-2015-0607-0028>
- U.S. EPA (U.S. Environmental Protection Agency). (2017a). Preliminary chemical data reporting (CDR) information on manufacturing, processing, distribution, use, and disposal: Cyclic aliphatic bromide cluster (HBCD). OCSPP. Support document. (EPA-HQ-OPPT-2016-0735).
- U.S. EPA (U.S. Environmental Protection Agency). (2017b). Preliminary information on manufacturing, processing, distribution, use, and disposal: Cyclic aliphatic bromide cluster (HBCD). (EPA-HQ-OPPT-2016-0735-0003). <https://www.regulations.gov/document?D=EPAHQ-OPPT-2016-0735-0003>
- U.S. EPA (U.S. Environmental Protection Agency). (2017c). Use and market profile for hexabromocyclododecane (HBCD). Draft.
- UNEP (United Nations Environment Programme). (2010). Hexabromocyclododecane draft risk profile (pp. 1-39). Europe.

<http://chm.pops.int/Convention/POPsReviewCommittee/hPOPRCMeetings/POPRC5/POPRC5Followupcommunications/HBCDInvitationforcommentsondraftRP/tabid/742/language/enUS/Default.aspx>

Weil, ED; Levchik, SV. (2009). Flame retardants for plastics and textiles practical applications. [online]: Carl Hanser Verlag GmbH & Co. KG.

XPSA (Extruded Polystyrene Foam Association). (2017). Preliminary information on manufacturing, processing, distribution, use, and disposal: Cyclic aliphatic bromide cluster (HBCD). OCSPP. Public comment. (EPA-HQ-OPPT-2016-0735-0017).

APPENDICES

Appendix A REGULATORY HISTORY

The chemical substance, HBCD, is subject to federal and state laws and regulations in the United States. The federal laws and regulations applicable to HBCD are listed along with the regulating agencies below in Table_Apx A-1. States also regulate HBCD through state laws and regulations, which are also listed within this section in Table_Apx A-2.

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Section 5(a)	Once EPA determines that a use of a chemical substance is a significant new use under TSCA section 5(a), persons are required to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use.	In September 2015, EPA promulgated a SNUR to designate manufacture or processing of HBCD for use as a flame retardant in consumer textiles (apart from use in motor vehicles) as a significant new use. Manufacturers (which includes importers) and processors are required to notify EPA 90 days before commencing the activity (80 FR 57293, September 23, 2015).
TSCA – Section 6(b)	EPA directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	Cyclic Aliphatic Bromide Cluster (HBCD) is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
TSCA – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	HBCD manufacturing (including importing), processing, and use information is reported under the CDR rule (76 FR 50816, August 16, 2011)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
TSCA – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed or imported into the United States.	HBCD (CASRN 25637-99-4 and CASRN 3194-55-6) was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process (60 FR 16309, March 29, 1995).
Emergency Planning and Community Right-to-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels.	EPA listed HBCD on the TRI under 81 FR 85440 effective November 28, 2016. The first TRI reporting deadline for HBCD is July 1, 2018.

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
Chemical of High Concern to Children	Maine classifies HBCD as a chemical of high concern (Maine 38 M.R.S.A. § 1693-A(1))
	Minnesota classifies HBCD as a chemical of high concern (Toxic Free Kids Act Minn. Stat. 2010 116.9401-116.9407)
	Washington requires manufacturers of children's products sold in Washington to report if their product contains certain chemicals of high concern to children, including HBCD. The law also bans from manufacture or sale, in the state, children's products or residential upholstered furniture containing >1,000 ppm of five flame retardants, including HBCD (Wash. Admin. Code § 173-334-130)
Other	In California, HBCD is listed as an initial informational candidate under California's Safer Consumer Products regulations, on the state's Proposition 65 list (Cal. Code Regs, tit. 22, § 69502.3, subd. (a))
	California lists HBCD as a designated priority chemical for biomonitoring. However, California has not yet started biomonitoring HBCD. (California SB 1379)
	The Oregon Department of Environmental Quality lists HBCD as a priority persistent pollutant and publishes use, exposure pathways and release data for HBCD (Oregon SB 737)

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by other Governments and Tribes

Country/Organization	Requirements and Restrictions
Canada	In October 2016, the Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012 (the Amendments) were published in the Canada Gazette, Part II: Vol. 150, No. 20 - October 5, 2016 and will come into force in December 2016. The Amendments include controls on HBCD that prohibit HBCD and certain products containing the substance. Time-limited exemptions for certain uses are included to allow industry to phase-out their use of HBCD. (Government of Canada)
European Union	HBCD is listed as a substance of very high concern (SVHC) and it is also listed under Annex XIV (Authorisation list) of European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). After August 21, 2015, only persons with approved authorization applications may continue to use the chemical (European Chemicals Agency)
	The Waste Electrical and Electronic Equipment (WEEE) directive in the European Union requires the separation of plastics containing brominated flame retardants prior to recycling (European Commission WEEE).
Japan	HBCD is subject to mandatory reporting requirements in Japan under the Chemical Substances Control Law (CSCL); specifically, Japan requires type III monitoring for all substances that may interfere with the survival and/or growth of flora and fauna (Ministry of Economy, Trade and Industry Japan).
Stockholm Convention on POPs	In May 2013, HBCD was added to the United Nation's Stockholm Convention list of POPs. The chemical is scheduled to be eliminated by November 2014 with specific exemptions for production and uses in expanded or XPS building insulation. As required by the convention, parties that use these exemptions must register with the secretariat and the exemptions will expire in November 2019 (Stockholm Convention POPs).

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for HBCD.

B.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration.

B.1.1 Manufacture (Including Import)

B.1.1.1 Domestic Manufacture

HBCD is manufactured in a closed system through the bromination of cyclododecatriene (CDT) in a suitable solvent at a process temperature of 20-70°C. The product of the reaction is a mixture of three principal HBCD isomers: alpha, beta and gamma. The resulting suspension is filtered, the solvent removed and the product dried. HBCD is produced in powder or pellet form ([EINECS, 2008](#); [Suh, 2000](#)).

B.1.1.2 Import

EPA has also not identified specific activities related to the import of HBCD at this time. EPA anticipates that imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and quality control (QC) samples may be taken for analyses.

B.1.2 Processing and Distribution

B.1.2.1 Processing as a Reactant/Intermediate

Processing as a reactant or intermediate describes the use of HBCD in a chemical reaction where the chemical is consumed in the manufacture of another chemical substance. HBCD is an intermediate in the inorganic chemicals manufacturing industry ([U.S. EPA, 2016b](#)).

B.1.2.2 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. HBCD may undergo several processing steps and the processing is dependent on its downstream incorporation into articles, which is discussed in the next subsection. EPA identified the following processing activities for HBCD.

Compounding into XPS Masterbatch

HBCD is compounded into an XPS masterbatch prior to being sold to XPS plastic converters, who then convert the XPS into a final article. Compounding likely occurs in a partially open process using extruders. In extruders, blends of polymer, additives and/or masterbatch are mixed either in the hopper or in tumblers and then fed into an extruder comprising one or two screws. These both shear the material and transport it through a heating regime. Volatile emissions may be produced and these are vented at various points in the extruder barrel ([OECD, 2004](#)). The compounded masterbatch may be converted into a final extrudate; however, EPA expects that the masterbatch is sent to industrial customers for further processing into a final article. HBCD concentration in the masterbatch is expected to be 50-70% ([EINECS, 2008](#)).

Manufacture of EPS Resin Beads

Manufacture of EPS resin beads is a batch process that involves suspension polymerization of styrene in water. Styrene is dispersed in water in the form of small droplets. Prior to combining the water with the organic phase, additives are introduced. Typically, these include suspension agents, free-radical-forming initiators and HBCD. HBCD, most often delivered in 25-kg paper bags with a plastic liner, is suspended at low temperatures in styrene prior to the addition of the water phase. Normally, the bags are emptied into an intermediate storage container from which the HBCD is transported via pipes and a weighing station prior the addition to the styrene ([EINECS, 2008](#)).

Within the monomer droplets (bulk), polymerization occurs while the reactor content is heated up and held at its reaction temperature. During this free-radical polymerization an expansion agent (e.g., pentane) is added to the reactor under pressure, where it is absorbed in the polymer droplets. In the final EPS beads, HBCD is incorporated as an integral and encapsulated component within the polymer matrix with uniform concentration throughout the bead. After complete conversion of the styrene monomer to EPS-beads, the reactor is cooled down and the beads are separated from the water by centrifugation. The decanted water, which could contain dissolved and dispersed HBCD, is reused and exchanged on an annual basis or less frequently. The EPS beads are dried, and thereafter classified into various size fractions and surface coated. These different grades are packed in bins or bags or transported in bulk trucks to the EPS-converters. The maximum concentration of HBCD in EPS beads is assumed to be 0.7% ([EINECS, 2008](#)).

Micronisation and Formulation for Textile Coatings

In textile coatings, there is sometimes a need for micronisation of the HBCD powder to produce an extra fine powder. Micronisation involves the grinding or milling of HBCD into particles that are 3-4 micrometers in particle size. Once the particle size is ideal, HBCD is further formulated into polymer-based dispersions. For the textile finishing industry, the dispersions are water-based and typically carried out in an open batch system. HBCD is added to a dispersion containing water, a polymer (such as latex, acrylates or polyvinylchloride [PVC]), a thickener and a dispersion agent ([EINECS, 2008](#)). Micronisation may occur in ball blenders, mills or other types of grinding processes. Coatings may also be formulated through a plastic processing and conversion step. These processes are described in OECD's ESDs on Plastic Additives ([OECD, 2004](#)).

Several ESDs published by OECD and Generic Scenarios published by EPA have been identified that may provide general process descriptions for other formulation processes that may be used for HBCD in adhesives, paint coatings and textile coatings. The processes involved are expected to be similar to those described above for polymer-based dispersions and may involve the unloading of HBCD powder from transport packaging directly into mixing equipment or into intermediate storage vessels, mixing of components either a batch or continuous system, QC sampling and final packaging of the formulation into containers.

B.1.2.3 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of HBCD-containing formulations or reaction products are

dependent on the article. EPA identified the following processing activities that incorporate HBCD and HBCD formulations or reaction products into articles.

EPS resin beads are converted into EPS products by expansion and then molding into rigid closed-cell foam. Once expanded, the beads are fused in a steam heated mold to form a specific shape or can be formed in a billet or block that can be hot-wire cut to its desired shape and size by users ([Priddy, 2006](#)).

HBCD powder or granules are incorporated into XPS products by extrusion. The HBCD powder or granules are unloaded into a hopper and fed into an extruder along with polystyrene resin, a blowing agent and other ingredients. A viscous plastic fluid is formed in the extruder and is discharged under pressure through a die onto a moving belt at ambient conditions. The blowing agent vaporizes, causing the polymer to expand into a desired shape or form, most likely continuous sheets (boards) of closed cell insulation. Alternatively, a vacuum is used in addition to the blowing agent to cause polymer expansion. XPS masterbatch is similarly converted into XPS products ([NICNAS, 2012](#); [EINECS, 2008](#); [Suh, 2000](#)).

HBCD may also be used in the manufacture of HIPS materials that may be used in electrical and electronic products, as described in Section 2.2.2. HIPS materials are made by incorporating rubber among other additives (such as HBCD) into polystyrene to impart increased toughness. HIPS pellets, HBCD powder or granules and other ingredients are pre-mixed and fed to the extrusion equipment. ([EINECS, 2008](#); [Priddy, 2006](#)). An alternative route for HIPS production is via an intermediate-compounding process in which general purpose HBCD-containing polystyrene masterbatch is prepared, followed by compounding this masterbatch with virgin HIPS material in a conversion step.

B.1.2.4 Recycling

As stated in Section 2.2.2, EPS and XPS foam in construction insulation materials is rarely recycled for numerous reasons, including that insulation waste is typically not separated from mixed waste stream. However, reuse and recycle does occur in the United States. At the end-of-life, polystyrene insulation boards (i.e., EPS and XPS foam insulation containing HBCD) may still have beneficial value for insulation. The insulation can be removed in whole and reused in the same capacity. Polystyrene insulation may also be demolished, melted and reformed into new insulation materials boards or other applications. Typically, polystyrene insulation containing HBCD can only be recycled into building insulation or other building applications ([U.S. EPA, 2014b](#)).

Electronic products (which may or may not contain HBCD) can also be recycled. HIPS materials constitute more than half the plastic materials recovered from household electronics ([Borchardt, 2006](#)). No information was identified that further described the processes used in recovering the plastics from electronics and how those plastics are reprocessed into other products.

B.1.3 Uses

B.1.3.1 Building/Construction Materials

A major use of HBCD is in XPS and EPS foam for continuous insulation applications such as in walls and roofs on the exterior of buildings, ceilings and subfloor systems. The materials may be incorporated into building products such as SIPs or insulating concrete forms (ICFs) or used in other below grade or geotechnical applications for foundations or highways or for dimensional stability or strength applications (e.g., insulated cold storage applications) ([U.S. EPA, 2017c, 2014b](#); [NICNAS, 2012](#)).

B.1.3.2 Electrical and Electronic Products

A reasonably foreseen minor use of HBCD is use as a flame retardant in the manufacture of electrical and electronic products. As discussed in Section 2.2.2, HBCD may be used in HIPS materials which in turn would be used in the assembly of electrical and electronic appliances such television sets, audio-visual equipment and refrigerator lining and would also be used in some wire and cable applications.

B.1.3.3 Floor Coverings

A reasonably foreseen minor use of HBCD is use as a flame retardant in the manufacture of floor coverings. As discussed in Section 2.2.2, HBCD may be used as a flame retardant in textile coatings for military, institutional and aviation applications, such as durable carpet tiles for hospitals or prisons.

B.1.3.4 Furniture and Furnishings

A reasonably foreseen minor use of HBCD is use as a flame retardant in the manufacture of furniture and furnishings. As discussed in Section 2.2.2, HBCD is used as a flame retardant in textile coatings for the manufacture of institutional furniture coverings.

B.1.3.5 Fabric, Textile and Leather Products

HBCD has minor uses in the manufacture of fabrics and textiles. As discussed in Section 2.2.2, HBCD is used as a flame retardant in coatings applied to automobile interior components (e.g., headliner, dashboard).

B.1.3.6 Other Products

A variety of other uses may exist for HBCD, including use in food packaging, bean bags, product packaging, toys, car seats, clothing, children's products, buoys for aquaculture, compact fluorescent bulbs and ventilations units. HBCD may also have minor uses in latex binders and paints ([EPA-HQ-OPPT-2017-0735-0003](#)) ([U.S. EPA, 2017b](#); [NICNAS, 2012](#); [EC/HC, 2011](#)).

It is unclear at this time the total volume of HBCD used in any of these applications. EPA has not identified any information to further refine the use of HBCD in these products; although, the use volume is likely minimal. More information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

B.1.4 Disposal

Releases from industrial sites to surface water (via direct discharge or indirect discharge through POTWs), air and landfill are expected during manufacture, processing, use, improper handling, improper storage or containment, product usage and disposal of HBCD or products containing HBCD ([U.S. EPA, 2014b](#); [NICNAS, 2012](#); [EC/HC, 2011](#); [EINECS, 2008](#)). Textile-related releases during product use are suspected of having a significant share of the total HBCD released into the environment ([EINECS, 2008](#)).

Demolished building materials are classified as Construction and Demolition (C&D) waste, which may be disposed in municipal solid waste landfills (MSWLFs) or C&D landfills ([U.S. EPA, 2014b](#)). Other products containing HBCD may also be disposed in MSWLFs. Also, as stated in Section 2.2.2, XPS foam may also be disposed of via waste energy plants.